DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 3, 2015

Medline Industries, Inc.
Claire Wellinghoff
Regulatory Affairs Specialist
One Medline Place
Mundelein, IL 60060

Re: K150238
Trade/Device Name: SensiCare® Sterile Powder-Free Polymer Coated Polyisoprene Surgical Glove, Coated with Aloe Vera (Tested for Use with Chemotherapy Drugs)-Natural Color
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's glove
Regulatory Class: Class I
Product Code: KGO
Dated: October 30, 2015
Received: November 9, 2015

Dear Ms. Claire Wellinghoff:

This letter corrects our substantially equivalent letter of November 27, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150238

Device Name

SensiCare Sterile Powder-Free Polymer Coated Polyisoprene Surgical Glove with Aloe Vera (Tested for Use with Chemotherapy Drugs)-Natural Color

Indications for Use *(Describe)*

The surgeon's glove is a device made of synthetic rubber latex intended to be worn by surgeons and /or operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes

The following chemicals have been tested with these gloves.

Carmustine Avg. 15.7 (15.7,16.3,17.0)
Cisplatin 240 min.
Cyclophosphamide (Cytoxan) 240 min.
Dacarbazine (DTIC) 240 min.
Doxorubicin Hydrochloride 240 min.
Etoposide (Toposar) 240 min.
Fluorouracil 240 min.
Ifosfamide 240 min.
Methotrexate 240 min.
Mitomycin C 240 min.
Paclitaxel (Taxol) 240 min.
Thiotepa Avg. 15.3 min. (15.3,15.3,15.3)
Vincristine Sulfate 240 min.

WARNING: Do not use with Carmustine and Thiotepa

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5
510(K) SUMMARY
AS REQUIRED PER 21 CFR 807.92(C)

K150238

Submitter / 510(k) Sponsor
Medline Industries, Inc.
1 Medline Place
Mundelein, IL 60060
Registration Number: 1417592

Contact Person
Claire Wellinghoff
Regulatory Affairs Specialist
Phone: 847-643-4071
Fax: 847-643-4482

Summary Preparation Date
November 27, 2015

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: SensiCare® Powder-Free Polymer Coated Polyisoprene Surgical Gloves, Sterile, Coated with Aloe Vera (Tested for Use with Chemotherapy Drugs)-Natural Color
Proprietary Name: SensiCare® Powder-Free Polymer Coated Polyisoprene Surgical Gloves, Sterile, Coated with Aloe Vera (Tested for Use with Chemotherapy Drugs)-Natural Color
Common Name: Surgeon's Glove
Device Class : I
Classification Name: Surgeon's Glove (21 CFR 878.4460)
Product Code: KGO
Classification Panel: General Hospital

Predicate Device
K111139 - Derma Prene IsoTouch Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs

Device Description
SensiCare® Sterile Powder-Free Polymer Coated Polyisoprene Surgical Glove, Coated with Aloe Vera (Tested for Use with Chemotherapy Drugs)-Natural Color is to function in the same manner as various

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other surgical gloves existing in industry today. The proposed SensiCare surgical glove is a disposable device made of synthetic rubber latex intended to be worn by surgeons and /or operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs. It has limited contact duration (≤ 24 hours), and is in direct contact with the skin. The proposed device is available in three design configurations; it is available in a smooth or micro-roughed (lightly textured) grip, as well as regular and custom fit. A coating of 100% Pure Freeze-Dried Aloe Vera gel and polyacrylate is applied to the inner surface of the glove. The polyacrylate and beaded cuff construction assist in glove stripping and donning. Please refer to the table below for a stand-alone comparison of the three glove design configurations that are the subject of this submission.

Stand-Alone Comparison Table

Device Characteristics	**Glove Design Configurations**			**Comparison Analysis**
	SensiCare with Aloe Surgical Glove	**SensiCare Lightly Textured (LT) with Aloe Surgical Glove**	**SensiCare Lightly Textured (LT) with Aloe, Custom Fit Surgical Glove**	
Glove Model Numbers	MSG1055 MSG1060 MSG1065 MSG1070 MSG1075 MSG1080 MSG1085 MSG1090	MSG1155 MSG1160 MSG1165 MSG1170 MSG1175 MSG1180 MSG1185 MSG1190	MSG1170C MSG1175C MSG1180C MSG1185C	N/A
Description	Powder-free Sterile Natural color	Powder-free Sterile Natural color	Powder-free Sterile Natural color	Same
Coating	Aloe Vera and Polyacrylate Coating	Aloe Vera and Polyacrylate Coating	Aloe Vera and Polyacrylate Coating	Same
Fit	Regular	Regular	Custom	Different
Texture	Smooth	Lightly Textured	Lightly Textured	Different
Device Class	Class I	Class I	Class I	Same
Material	Polyisoprene	Polyisoprene	Polyisoprene	Same
Finger Thickness	0.10 mils	0.10 mils	0.10 mils	Same
Packaging	25/box; 100/case	25/box; 100/case	25/box; 100/case	Same
Labeling	Glove Pouch in dispenser box	Glove Pouch in dispenser box (	Glove Pouch in dispenser box	Same

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Size	5.5 6 6.5 7 7.5 8 8.5 9	5.5 6 6.5 7 7.5 8 8.5 9	7 7.5 8 8.5	Same * *Fewer sizes offered for SensiCare with Aloe Surgical Glove Lightly Textured (LT), Custom Fit
Labeling	Glove Pouch in dispenser box	Glove Pouch in dispenser box	Glove Pouch in dispenser box	Same
Residual Powder	Meets ASTM D6124-06 & definition for Powder-Free; ≤ 2 mg/glove	Meets ASTM D6124-06 & definition for Powder-Free; ≤ 2 mg/glove	Meets ASTM D6124-06 & definition for Powder-Free; ≤ 2 mg/glove	Same
Primary Irritation	Meets ISO 10993-10 No Dermal Irritation Potential	Meets ISO 10993-10 No Dermal Irritation Potential	Meets ISO 10993-10 No Dermal Irritation Potential	Same
Dermal Sensitization	Meets ISO 10993-10 No Sensitization Potential	Meets ISO 10993-10 No Sensitization Potential	Meets ISO 10993-10 No Sensitization Potential	Same
Performance	Meets ASTM D3577-09e	Meets ASTM D3577-09e	Meets ASTM D3577-09e	Same

CONFIDENTIAL

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Intended Use

The surgeon's glove is a device made of synthetic rubber latex intended to be worn by surgeons and /or operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes

The following chemicals have been tested with these gloves.

Carmustine	Avg. 15.7 (15.7,16.3,17.0)
Cisplatin	240 min.
Cyclophosphamide (Cytoxan)	240 min.
Dacarbazine (DTIC)	240 min.
Doxorubicin Hydrochloride	240 min.
Etoposide (Toposar)	240 min.
Fluorouracil	240 min.
Ifosfamide	240 min.
Methotrexate	240 min.
Mitomycin C	240 min.
Paclitaxel (Taxol)	240 min.
Thiotepa	Avg. 15.3 min. (15.3,15.3,15.3)
Vincristine Sulfate	240 min.

WARNING: Do not use with Carmustine and Thiotepa

Summary of Technological Characteristics

The information within this submission demonstrates that there are no significant differences in technological characteristics of the subject device and the predicate devices. The subject device has the same functionality and indications as the predicate device listed. The comparative table below (Table 1) offers details pointing to similarities and differences between the proposed and predicate device.

Table 1. Predicate Comparison Table

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis: Substantially Equivalent?
Product Name	SensiCare® Sterile Powder-Free Polymer Coated Polyisoprene Surgical Glove, Coated with Aloe Vera (Tested for Use with Chemotherapy Drugs)-Natural Color	Derma Prene® Isotouch® Green Sterile Powder-Free Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs	N/A
Design Configurations	SensiCare With Aloe Surgical Glove SensiCare Lightly Textured (LT) With Aloe Surgical Glove SensiCare Lightly Textured (LT) With Aloe, Custom Fit Surgical Glove	N/A	N/A
510(k) Reference	TBD	K111139	N/A
Product Owner	Medline Industries	Ansell Healthcare Products LLC	Different
Product Code	KGO	KGO	Identical
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Identical
Device Class	Class I	Class I	Identical
Intended Use	The surgeon's glove is a device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs. Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes The following chemicals have been tested with these gloves. Carmustine Avg. 15.7 (15.7,16.3,17.0) Cisplatin 240 min. Cyclophosphamide 240 min. Dacarbazine (DTIC) 240 min Doxorubicin Hydrochloride 240 min. Etoposide (Toposar) 240 min. Fluorouracil 240 min. Ifosfamide 240 min. Methotrexate 240 min. Mitomycin C 240 min. Paclitaxel (Taxol) 240 min. Thiotepa Avg. 15.3 min. (15.3,15.3,15.3) Vincristine Sulfate 240 min. WARNING: Do not use with Carmustine and Thiotepa	These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs. Chemotherapy Drug Permeation (average breakthrough detection time in minutes) (ASTM D6978-05) *Carmustine 15.5 Cyclophosphamide >240 Doxorubicin Hydrochloride >240 Etoposide (Toposar) >240 5-Fluorouracil >240 Paclitaxel (Taxol) >240 *ThioTEPA 15.5 Methotrexate >240 Vincristine Sulfate >240 Please note that Carmustine and ThioTEPA have an extremely low permeation time of 15.5 minutes.	Substantially Equivalent

Table 1. Predicate Comparison Table

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis: Substantially Equivalent?
Device Description	Is a disposable device made of synthetic rubber latex intended to be worn by surgeons and /or operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs. It has limited contact duration (≤ 24 hours), and is in direct contact with the skin The proposed device is available in three design configurations; it is available in a smooth or micro-roughed (lightly textured) grip, as well as regular and custom fit. A coating of 100% Pure Freeze-Dried Aloe Vera gel and polyacrylate is applied to the inner surface of the glove. The polyacrylate and beaded cuff construction assist in glove stripping and donning.	Is a disposable device made of synthetic latex rubber that is intended to be worn by operation room personnel to protect a surgical wound from contamination, and is tested for use with chemotherapy drugs. A coating of Aliphatic Polyester Polyurethane is applied to the inner surface of the glove to make donning easy.	Substantially Equivalent
Powder-Free	Yes. Meets ASTM D6124-06 and definition for Powder-Free; ≤ 2 mg per glove	Yes. Meets definition for Powder Free; ≤ 2 mg per glove	Substantially Equivalent
Coating	Aloe Vera and Polyacrylate coating	Polyurethane coating	Different (See Reference Device K102177)
Materials	Polyisoprene	Polyisoprene	Identical
Color	Natural Colored	Green	Different (See Reference Device K102177)
Sterility vs. Non-Sterile	Sterile	Sterile	Identical
Disposable vs. Non-Disposable	Disposable	Disposable	Identical
Single Use vs. Reusable	Single Use	Single Use	Identical

Table 1. Predicate Comparison Table

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis: Substantially Equivalent?
Sizes	5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	Identical
Freedom from Holes	Meets ASTM D3577-09e & ASTM D5151-06	Meets ASTM D3577-09e & ASTM D5151-06	Substantially Equivalent
Dimension with Tolerances	Meets requirements of: ASTM D3577-09e FDA Medical Glove Guidance Manual (See Table 2 below)	Meets requirements of: ASTM 3577-09e FDA Medical Glove Guidance Manual	Substantially Equivalent
Performance	Meets ASTM D3577-09e	Meets ASTM D3577-09e	Substantially Equivalent
Dimensions and Physical Properties	Meets ASTM D3577-09e	Meets ASTM D3577-09e	Substantially Equivalent
Tested for Use W/ Chemotherapy Drugs	Meets ASTM D6978-05	Meet ASTM D6978-05	Substantially Equivalent
Biocompatibility	Meet ISO 10993-10; Dermal Sensitization and Primary Skin Irritation Study	Meet ISO 10993-10; Dermal Sensitization and Primary Skin Irritation Study	Substantially Equivalent
Labeling	Glove Pouch in Dispenser Box	Glove Pouch in Dispenser Box	Identical

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Table 2. Dimensions and Tolerances

Series	MSG10XX	MSG11XX	MSG11XXC
	Length, mm (minimum)	Length, mm (minimum)	Length, mm (minimum)
Size			
5.5	278	278	N/A*
6	280	280	N/A*
6.5	280	280	N/A*
7	283	283	283
7.5	287	287	287
8	288	288	288
8.5	290	290	290
9	290	290	N/A*
	Width, mm	Width, mm	Width, mm
Size			
5.5	70 ± 6	70 ± 6	N/A*
6	76 ± 6	76 ± 6	N/A*
6.5	83 ± 6	83 ± 6	N/A*
7	89 ± 6	89 ± 6	89 ± 6
7.5	95 ± 6	95 ± 6	95 ± 6
8	102 ± 6	102 ± 6	102 ± 6
8.5	108 ± 6	108 ± 6	108 ± 6
9	116	116	N/A*

*Glove model not offered in this size

Summary of Non-Clinical Testing

The safety and effectiveness of the subject device is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this submission. The subject device meets the applicable requirements for surgeon's gloves with regard to the dimensions and sizes, physical properties, freedom from holes, and powder residues as found in the following standards: ASTM D3577-09e, ASTM D5151-06, and ASTM D6124-06. In addition, the proposed device demonstrates device safety in accordance with relevant ISO 10993-10 test methods as there was no dermal sensitization and primary skin irritation was observed. Additionally, the proposed surgical glove was tested for permeation by chemotherapy drugs in accordance with ASTM D6978-05. Results show that the proposed surgical glove meets the criteria in accordance with ASTM D6978-05.

Summary of Clinical Testing

Not applicable. No clinical testing was performed.

Conclusion

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In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, the SensiCare® Powder-Free Polymer Coated Polyisoprene Surgical Glove, Sterile, Coated with Aloe Vera (Tested for Use with Chemotherapy Drugs)-Natural Color is as safe, as effective and performs as well as the predicate device K111139 based on the conclusions drawn from the nonclinical and clinical tests. The subject device has been tested against the ASTM and ISO standards listed, and met the requirements in accordance with those standards. Additional comparisons found herein show that the subject device is substantially equivalent to the predicate.